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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,245	12/18/2001	Yoshiaki Fukuda	46/224	8337
20736	7590	01/11/2006	EXAMINER	
MANELLI DENISON & SELTER 2000 M STREET NW SUITE 700 WASHINGTON, DC 20036-3307			GAMBEL, PHILLIP	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/018,245

Applicant(s)

FUKUDA ET AL.

Examiner

Phillip Gambel

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-17 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 14-17 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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### Detailed Action

1. Applicant's amendment, filed 10/14/05, has been entered.  
Claims 18-23 have been canceled. Claims 1-13 have been canceled previously.  
Claims 14-17 have been added.

Claims 14-17 are under consideration in the instant application.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.  
This Action will be in response to applicant's amendment, filed 10/14/05.  
The rejections of record can be found in the previous Office Action, mailed 4/15/05.
3. Applicant's amendment, filed 10/14/05, amending the application to be in compliance with the Sequence Rules is acknowledged.

Again, applicant is required to review the entire instant application to make sure that the instant application is in compliance with the Sequence Rules.

For example, the 5'-primer in the paragraph starting at page 16, line 17 and ending a page 17 ,line 20, amended on 10/14/05 does not have a SEQ ID NO.

Again, if the instant application does not have an appropriate SEQ ID NO: for each disclosed sequence, then applicant must comply with the Sequence Rules as set forth in 37 CFR 1.821-1.825.

4. Acknowledgment is made of applicant's claim for foreign priority based on the Japanese patent application NO. 2000-117394, filed 4/19/00 and indicated in WO 01/792298.

A copy of the Japanese patent application NO. 2000-117394, filed 4/19/00 as required by 35 U.S.C. 119(b), has been placed in the instant file.

Also, given the absence of a certified translation of the foreign priority papers, the examiner cannot determine whether the Japanese patent application NO. 2000-117394, filed 4/19/00, provides sufficient support under 35 USC 112, first paragraph, written description and enablement for the instant claims.

Therefore, the priority date of the instant application still appears to be the priority date of PCT/JP01/03308, filed 4/18/01.

5. The Drawings, filed 12/18/01, appear to be acceptable.
6. Again, the title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention (e.g. TNF $\alpha$ -specific 3B10 antibodies).

Also, applicant should avoid the use of "novel" as all patents are presumed to be novel and unobvious.

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7. Applicant is reminded that the Abstract should be no longer than 150 words and not exceed 15 lines of text. See MPEP 608.01(b).

8. Applicant's amended claims, filed 10/14/05, have obviated the previous objection and rejections under 35 U.S.C. 112, first and second paragraphs.

9. Claims 14-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Nagahira et al. (J. Immunological Methods 222: 83-92 (1999) (1449; #RR) (see entire document) essentially for the reasons of record.

Applicant's arguments, filed 10/14/05 have been fully considered but have not been found convincing essentially for the reasons of record.

Applicant essentially argues asserts that Nagiahra et al. fails to disclose the amino acid sequences of CDRs of the anti-TNF $\alpha$  antibody 3B10.

As pointed out previously, Nagahira et al. teach the same or nearly the same humanization of the same neutralizing anti-human TNF $\alpha$  3B10 antibody, as disclosed in the instant application and claimed (e.g. see Abstract, Materials and Methods, Results, including Figures 1 and 2 as well as Table 1).

Again, applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced antibodies.

While the prior art Nagahira et al. may have examined the role of framework changes on antibody specificity and immunogenicity, the prior art 3B10 and humanized 3B10 antibody have the same CDR sequences as that claimed in the absence of evidence to the contrary.

Comparison of the claimed antibodies with the prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be related and conduct comparisons.

The Courts have held that there is no requirement that those of ordinary skill in the art know of the inherent property. See MPEP 2131.01(d) and MPEP 2112 - 2113 for case law on inherency.

The prior art and the instant application have made the same recombinant neutralizing anti-human TNF $\alpha$  3B10 antibody by using the same neutralizing anti-human TNF $\alpha$  3B10 antibody. For example, compare the prior art disclosure with the Examples disclosed in the instant specification.

Again, it is the burden of applicant to show that inherency is not involved here between applicant's prior art teaching of the same or nearly the same appellants have the burden of showing that inherency is not involve.

Applicant's arguments have not been found persuasive.

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10. No claim is allowed.

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Phillip Gambel, Ph.D., J.D.

Primary Examiner

Technology Center 1600

January 3, 2006